REMARKS

The Examiner is thanked for the courtesy of the personal interview held November 15, 2004 which was attended by the undersigned attorney and one of the inventors, Stephen Hunyor.

Prof. Hunyor explained the present invention by demonstrating a model of the heart actuator device of the present invention (retained by the Examiner) and explained the differences between claim 1 of the present invention and Wardle and Hotei. Prof. Hunyor also showed the Examiner a short video in which the heart of a sheep in a harness is arrested and then resuscitated several times. Finally, the Examiner was provided with a copy of an article in the Wall Street Journal of November 8, 2004 concerning the cardiac "sock", copy attached.

Claim 1 has been amended as discussed at the interview, *inter alia*, to provide a limitation to show the affixed feature provides for decompression of the heart as well as compression of the heart. In view of the claimed decompression feature, "heart compressing wall" has been changed to --proximal wall-- throughout the claims. Minor amendments have been made to claims 7 and 14. As agreed, no claims have been submitted with trademarks set forth therein.

An identification of the general trust of the principal argument presented to the Examiner as well as an elaboration on some of these arguments follows. The device which is the subject of the present invention is for use in apparatus for actively assisting in direct cardiac compression. The apparatus comprises in essence these components:

(a) an actuator (that is the device of the present invention),

(b) a control system based on ECG or pressure or operating without either trigger signal, and

(c) an energy source.

The important features of the heart actuator device of the present invention as defined by claim 1, which is used in an active heart assist apparatus, include:

(i) a paddle-like main body which includes a proximal wall (heart compressing/decompressing wall) which in use is affixed to at least a region of the heart; and

(ii) the main body includes a distal wall and the proximal wall is movable so as to compress and decompress the region of the heart to which the main body is affixed.

These features provide for significant advantages. First, because the paddle-like main body is affixed to the heart, it does not interfere with size changes in the heart, and, further, because the heart is generally unconstrained, the problems with devices that encase the heart are avoided. It also allows vacuum suction to rapidly actuate the paddles so that the paddles can be individually actuated. These problems are described in some detail in the paragraphs bridging pages 6 and 7 of the specification.

Additional advantageous features of the device in its various preferred forms are defined in the dependent claims. For example, claims 2-4 define the main body as having two major walls, one of which defines the proximal wall and the other defining the distal wall, the proximal wall being curved inwardly and the distal wall being curved outwardly. Furthermore, the distal wall has a greater degree of stiffness than the proximal wall. This particular structure enables the proximal wall to conform to that part of the heart to which it is affixed regardless of any variation in the size of the heart. The relative rigidity of the distal wall to the proximal wall ensures that a positive compression of the heart is effected by the proximal wall.

A further particularly advantageous feature of the device in a preferred embodiment of the present invention is the provision of the device of the present invention of biocompatible material for affixing the proximal wall to the heart.

Claims 1-7, 14, 15 and 25-33 are rejected as anticipated by Wardle. Claims 16-24 are rejected as obvious over Wardle in view of Smith and further in view of Heilman et al. These rejections are respectfully traversed.

The apparatus described in Wardle is entirely different to the device of the present invention. The Wardle apparatus is in essence a passive girdling device for supporting the heart.

The Wardle device includes a frame 12 which is sutured to the heart. In use, the heart is encased almost in its entirety within the frame 12. Attached to the frame 12 are a series of inflatable pockets 22 each of which has associated with it a highly elastic recoil balloon 24. The inflation pocket 22 is on the inside of the frame 12 and the recoil balloon 24 is on the outside of the frame 12. Each associated pocket 22 and balloon 24 are in fluid communication with one another via ports 20 in the frame 12. There are various embodiments described but, in essence, they are all of the same general construction to that described above.

The purpose of the pockets 22 is to support the wall of the heart ventricle. The pockets 22 are not attached to the heart wall. The operation of the device is described in the first paragraph of column 9. As described when the device is first placed on the heart, the pockets are completely collapsed. Fluid is then introduced into the space between the pocket and its associated balloon and the pocket is brought into contact with the heart. As is described, the pockets act as an external restraining force.

Basically, the Wardle device is specifically for contaminant of the heart. It surrounds or encases the heart so as to confine and control ventricular diastolic expansions. The inflation pockets are primarily provided to allow for adjustment of the constraint on the heart. Thus, the Wardle device suffers all of the disadvantages of the prior art devices which constrain the heart as discussed in the patent specification.

As described above, the Wardle device includes a more rigid inflation pocket made of high strength, low elasticity material in contact with the heart (col. 4, lines 40-48). The recoil balloon (24 in Fig. 1) on the non-heart contacting side is fabricated from a thin, high elasticity material (col. 4, line 66 to col. 5, line 1). If active pressure is applied to the device as described in col. 11, lines 10-29, it would first and foremost inflate the device away from the heart instead of compressing the heart. This is entirely contrary to the device of the present invention.

Because the pockets are not attached to the heart, there would be a tendency to set up an irritation at the heart surface interface due to the continued mechanical contact and rubbing. This could cause damage to the surface coronary arteries and/or interface with coronary blood flow. Such irritation is likely to cause production of serious fluid which can be of substantial volume. Despite the provision of "port holes" (col. 4, lines 37-39), such an effusion can collect in pockets inside or around the "containment" device (pericardial effusion) and even result in serious disturbance in the heart's ability to fill or empty. There are comparable clinical disease states which can create medical emergencies (e.g., perdicardial tamponade).

The Wardle patent specification contemplates an arrangement that will provide some active assist during systole. Clearly, the pressure applied to the heart during systole would come from the recoil component of the inflatable pockets on the outside of the "containment frame or structure." The pressure build-up during diastole in the outer recoil balloons is, in the applicant's view, unlikely to be sufficient to lend any support during systole. The pressure in these external inflatable pockets would come from the force of heart dilation during diastole. If at this phase of

the heart's cycle the pressure is more than 20 mmHg inside the heart, its diastolic function is compromised to a degree that the heart is "strangled" by the device. Also, the pressure throughout the circulation settles at around 20 to 30 mmHg when the heart stops (known as "Mean Circulatory Pressure"), making the Wardle device quite ineffective during this not infrequent occurrence in patients with severe heart failure, the group for which the device is intended.

In conclusion, the Wardle patent describes a complicated passive heart assist device which has many drawbacks. The Wardle patent aims to allow for adjustments in volume and pressure inside the containment frame and the inflation pockets to accommodate different sized hearts. There are strong *prima facie* grounds for concluding that the Wardle device is quite unsuited for use as an active device for the failing heart.

The secondary references are cited to show monitoring the mechanical and electrical activity of the heart. However, these references clearly do not show the important features of the present invention.

Hotei discloses a device with a hard base plate of epoxy resin which is oval in shape like a cup. The soft polyurethane membrane is not affixed to the heart. Rather, a felt fabric is fixed around the base plate with glue and used to attach the device to the free wall of the left ventricle. Thus, the Hotei device differs significantly from the present invention wherein the proximal wall is affixed to the heart so that it can compress and decompress the heart. Moreover, in preferred forms of the present invention, the distal wall is not rigid and is moveable.

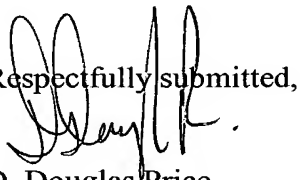
Claims 8, 9, 11 and 12 (now cancelled) have been rewritten in independent form as claims 34-37, respectively, including all of the limitations of the base claim and any intervening claims. Thus, claims 34-37 are in condition for allowance.

In view of the foregoing, early and favorable action is respectfully requested.

A Petition For Extension Of Time is being filed concurrently herewith.

The Commissioner is hereby authorized to charge any fees due in connection with the present Amendment to Deposit Account 19-4293.

Respectfully submitted,



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By Merissa Marr

Pixar Animation Studio's "The Incredibles" thundered into movie theaters with an estimated $70.7 million of domestic ticket sales over the weekend, just beating the studio's previous blockbuster "Finding Nemo" and keeping its gleaming track record of megahits intact.

Kicking off a fiercely competitive holiday season, the strong start out the gate by "The Incredibles" sets a high bar for "The Polar Express," the expensive adaptation of the Christmas-themed book from **Time Warner** Inc.'s Warner Bros., which makes its bow Wednesday.

"This is our highest-grossing animated movie yet," said Chuck Viane, head of distribution at **Walt Disney** Co.'s studio, which co-finances Pixar's movies and distributes them through its Buena Vista unit. The opening-weekend tally wasn't enough to surpass top-ranked animated movie "Shrek 2," but "The Incredibles" did sneak into second place ahead of "Finding Nemo" which opened with $70.2 million.

After a spotless run of five blockbusters and the monster success of rival studio **DreamWorks Animation SKG**'s "Shrek 2," Pixar has been under pressure to produce another hit. As word spread last week that "The Incredibles" was shaping up for a big debut, the Emeryville, Calif., studio's shares jumped sharply Friday before settling at $84.45, up $3.59 in 4 p.m. Nasdaq Stock Market trading.

The PG-rated movie, about a superhero family coping with life in suburbia, is the second to the last under Pixar's co-financing and distribution deal with Disney. After fraught discussions over renewing that deal, Pixar has been informally talking to other studios, although it isn't yet negotiating with others and could still return to the Disney table.

"We don't have to have a new deal in place until next year," said Pixar Chief Executive Steve Jobs. "We've had offers of strong interest and we're taking our time getting to know people." As part of a new deal, Mr. Jobs says Pixar wants to fully finance its movies.

While "The Incredibles" beat the opening of "Finding Nemo," the studio played down its chances of topping the overall success of that movie, a summer release that took in $864 million at the box office world-wide. "We'd be thrilled if this movie did the same business as 'Monsters, Inc.,' which was released in No-

The Wall Street Journal Nov 8 2004 B4

Cardiac 'Sock' Lends Support To Failing Hearts, Study Says

By Ron Winslow

Call it support hose for the heart.

A new device that encases the heart in a mesh sock appears to help prevent or heal structural changes that cause the organ to weaken and work inefficiently in patients with heart failure.

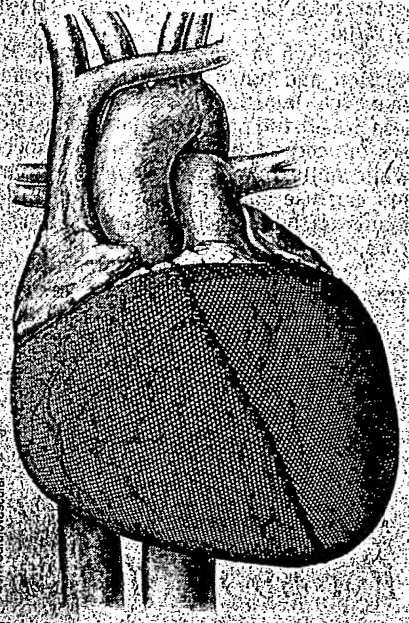
In a randomized study involving 300 heart-failure patients, 38% of those who had the sock implanted around the heart had improvements in their condition, compared with 27% who were treated with the best available medical therapy, researchers said. In addition, 37% of the sock patients "worsened," compared with 45% of patients on medical treatment alone. Median follow-up was 22 months.

Heart failure is a debilitating and often fatal disease characterized by a weakened heart muscle that becomes progressively inefficient in pumping blood to the body, and causes the left ventricle, the main pumping chamber, to grow abnormally. Patients are often left fatigued and short of breath. About five million Americans have heart failure and a half-million new cases are added each year.

While medicines and electrical pacing and defibrillators help treat symptoms and prevent sudden death from heart failure, there aren't any treatments aimed specifically at the structural anomalies, said Douglas L. Mann, cardiologist at the DeBakey Veterans Affairs Medical Center in Houston, who led the trial and is a consultant for the sock's manufacturer.

The sock—which requires surgery to implant—is called the CorCap Cardiac Support Device and is being developed by **Acorn Cardiovascular** Inc., a closely held company in St. Paul, Minn. Acorn expects to file a marketing application with the Food and Drug Administration by early next year.

Dr. Mann said the device works by relieving stress on the heart, enabling it to heal and recover much of its normal shape. "It returns from a basketball shape to a more mechanically efficient



The CorCap, *made by Acorn Cardiovascular, is a fabric mesh device that is implanted around the heart to support the heart muscle.*

football shape," Dr. Mann said. He presented the findings at the annual scientific meeting of the American Heart Association in New Orleans.

Improvement was determined based on a composite of whether patients survived, needed a major cardiac procedure such as a heart transplant, or had other evidence of progression of their disease.

Dr. Mann said the sock didn't lead to a significant improvement in ejection fraction, the percent of blood that is pumped out of the left ventricle during a beat and a widely used measure of the strength of the heart. Dr. Mann said he and other doctors believe improvements in structural changes are a better measure of the effectiveness of the device.

Nintendo Faces Off With Sony